

REMARKS

Claims 1, 3 to 13, 22, and 27 are in the application.

Claims 1, 3, 4, 13, 22 and 27 have been amended to better present the claims for allowance and for the appeal, if necessary. Support for the amendments lies in the specification on page 5, lines 15 to 17. No new matter is believed added.

Rejection of Claims under 35 U.S.C. § 103 (a).

Claims 1, 3 to 13, 22, and 27 are rejected under 35 USC §103(a) as being unpatentable over De Wille et al. (US 5,597,595) or Burkes et al. (US 5,335,837). Applicant respectfully traverses this rejection.

The presently claimed invention is believed to distinguish Applicants invention over the cited De Wille et al. and Burkes et al references.

The Examiner discusses the De Wille et al. reference as showing a molar ratio of calcium to acid of 0.56 in Example 7 based upon the conjecture that as the De Wille '595 patent recites 60% lactic acid in certain embodiments and 88% lactic acid incorporation in others, the skilled artisan would be taught to prepare the formulation of Example 7 using 88% instead of 60% Lactic acid. In doing such a molar ratio of 0.56 would thereby be obtained. While this is a hindsight argument as De Wille et al. could have drafted such an embodiment and did not. It is not relevant as the De Willie et al. patent does not direct the skilled artisan to a balancing of the factor herein (calculation of the calcium:acid molar ratio maintenance of the final pH of the composition) for the end use of these compositions. There is no recognition that such a combination of factors would be inhibit or reduce of tooth erosion, but instead direct themselves to dietary supplementation compositions.

Applicants have amended claim 1 and 22 to recite the molar ratio of calcium and acid to be present in the range of 0.3 to 0.55 mol per mol of acid. Claim 4 has been amended to recite about 0.4 mol calcium per mol of acid, and Claim 13 has also been amended to recite a value of about 0.5 mol calcium per mol of acid. These ranges of ratios are not taught nor suggested by the De Wille et al. patent.

The Examiner does not discuss Applicants arguments re the Burkes et al. '837 patent in the office action. However, it should be noted that in Applicants previous January 29, 2004 response a detailed description of the molar ratios of the composition of the Burkes et al. '837 patent were presented. Then and more certainly now, in the amended claims, the molar ratio is outside those described in the Burkes

et al. patent. For instance, the lowest ratio which one can calculate in the Burkes et al. patent is in Example 5, which has a ratio of about 0.63 and for Examples 1 and 4 a ratio of 0.65 is determined. The claims, as presently amended, recite 0.3 to 0.55 and more specifically about 4 (claims 4), and about 0.5 (claim 13). These ratios are not described nor suggested by the Burkes et al. patent. Additionally, the second limitation of Claim 1, that the effective pH of the composition is from 3.5 to 4.5, is not met by the Examples of Burke et al. patent.

Neither the Burkes et al. nor the De Wille et al. patents direct the skilled artisan to a produce a formulation directed to reduction of tooth erosion in a solid or semi-solid composition for oral use. While De Wille can be misconstrued to make a formulation which is close in molar ratio to that of Applicants claimed herein, the De Wille et al. patent lacks the necessary motivation to do so. It is Applicant who has determined that by requiring only the addition of calcium to an acidic composition in a particular molar ratio, and maintaining the pH of that effective composition, can tooth erosion be reduced.

The concept of identifying a composition which is effective against tooth erosion by reference to calcium:acid molar ratio and their pH in solid or semi-solid compositions is believed to be novel and inventive over the cited De Wille et al. and Burkes et al references.

As previously stated, both the De Wille et al. and the Burkes et al. patents require at least two modifications of their respective compositions to meet the limitations of the claims herein. In some instances, both the molar ratio and the pH must be modified, in some just one of the factors. There is, however, no motivation in these references to direct the skilled artisan to optimize these factors, either to improve the stability of CCM, or for Vitamin D supplementation. Since the Burkes et al. and the De Willie et al. applications relate to calcium supplementation, if the skilled addressee were to set out to optimize the compositions disclosed therein (as asserted by the Examiner), he would not arrive at compositions falling within the scope of the claimed invention. The skilled artisan's objective would be to add more calcium. By adding more calcium the mole ratio will be higher than the ratios already calculated from the Examples in Burkes et al. and De Wille et al., e.g. higher than the 0.83 of Example 7 in Burkes et al. and more distant from the claimed range of 0.3 to 0.6.

The absolute amount of calcium present in a composition prepared according to the invention herein is not critical. It is the molar ratio of calcium to total acids. It is this recognition, *the molar ratio of calcium to total acid* in a solid or semi-solid composition, which is the heretofore an unrecognized invention to reduce tooth erosion.

Therefore, in view of these remarks Applicant respectfully requests that the rejection to the claims under 35 USC §103 be withdrawn.

CONCLUSION

Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned at the number below. It is not believed that this paper should cause any additional fees or charges to be required, other than expressly provided for already. However, if this is not the case the Commissioner is hereby authorized to charge Deposit account 19-2570 accordingly.

Respectfully submitted,



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